Ontario Shores
Centre for Mental Health Sciences

REB STANDARD OPERATING PROCEDURES MANUAL

Name of SOP: Terms, Definitions and acronyms
REB SOP # 002

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Purpose:
The purpose of this document is to describe and outline the terms, definitions and acronyms utilized in the standard operating policies and procedures (SOPs) established by Ontario Shores Research Ethics Board (OSREB).

Scope:
This SOP pertains to Research Ethics Boards (REB) that review human participant research in compliance with applicable regulations and guidelines.

Description:
The Research Ethics Office (REO) administratively supports the duties of Research Ethics Board Members as outlined in the Terms of Reference of Ontario Shores' Research Ethics Board. SOPs describe the process and procedures to be followed and documented to assure that ethical standards are followed uniformly and consistently applied by the REB in fulfilling its mandate. The terms referenced here facilitate compliance with the principles, guidelines and regulations applicable to the ethical review, conduct and oversight of research involving humans, personal health information and/or human biological materials. This ensures the protection of rights and welfare of the human participants involved in research as envisaged in TCPS 2.

Definitions (including acronyms in alphabetical order):

Access Log: a document that records the names, signatures of persons accessing any records or the identifying information of the research participants, and the date on which this occurred.

Acting Chair: fulfills the duties of the Chair of REB, when the Chair is either not available, or must declare conflict of interest in reviewing a specific application. The Acting Chair is recruited by the REB Chair and is an REB member in good standing with a minimum of one year experience on an REB.

Amendment: a written description of modification(s) of the previously approved research. The amendment application that include amendment checklist, report form and modified documents (clean and track change versions) must be submitted by principal investigator (PI) to the REB for review and approval.

Appeal mechanism: A procedure established by an institution to promptly handle a researcher's appeal of a research ethics board (REB) decision. An ad hoc or permanent appeal committee, which reflects a range of expertise and knowledge similar to that of the REB, is established or appointed by the same authority that established the REB.

Approval Period: the standard REB approval period is calculated as the one-year anniversary from the full board meeting date when the study was last reviewed and which resulted in approval (e.g. September 25, 2013 to September 24, 2014),or for delegated review, the date the delegated approval was granted. When the REB determines that a more frequent review is required, the approval period will be determined by the chair and/or REB (i.e., six months from the date of the REB meeting).

Authorized Signatory: individual(s) authorized to sign documents on behalf of the REB. Also referred to as "signing authority". The signing authority is determined by the chair of REB, when she/he is not available for a protracted period due to illness or leave of absence.

Autonomy: The capacity to understand information and to be able to act on it voluntarily; the ability of individuals to use their own judgment to make decisions about their own actions, such as the decision to consent to participate in research.

Biobank: A collection of human biological materials. It may also include associated information about individuals from whom biological materials were collected.

Board: "Board" refers to the Board of Directors for Ontario Shores Centre for Mental Health Sciences (Ontario Shores). Board shall always be prefaced with the corporation name "Ontario Shores"

Capacity: The ability of prospective or actual participants to understand relevant information presented (E.g. purpose of the research, foreseeable risks, and potential benefits), and to appreciate the potential consequences of any decision they make based upon this information.

Chair, REB: Chair of the Research Ethics Board (REB) will be nominated and approved by the "board" as outlined in the REB Terms of Reference.

Clinical equipoise: The existence of a genuine uncertainty on the part of the relevant expert community about what therapy or therapies are most effective for a given condition.

Clinical trial: Any investigation involving participants that evaluates the effects of one or more health-related interventions on health outcomes.

Coercion: An extreme form of undue influence, involving a threat of harm or punishment for failure to participate in research.

Collaborative research: Research that involves the cooperation of researchers, institutions, organizations and/or communities, each bringing distinct expertise to a project, and that is characterized by respectful relationships. See "Community-based research" and "Participatory research."

Community: A group of people with a shared identity or interest that has the capacity to act or express itself as a collective. A community may be territorial, organizational, or a community of interest.

Community-based research: Research conducted at a community site that focuses not only on individuals but on the community itself. Community-based research may be initiated by the community independently or in collaboration with a researcher. See "Collaborative research" and "Participatory research."

Community engagement: A process that establishes an interaction between a researcher (or a research team) and a community with regard to a research project. It signifies the intent of forming a collaborative relationship between researchers and communities, although the degree of collaboration may vary depending on the community context and the nature of the research.

Concern for Welfare: A core principle of TCPS 2 policy that requires researchers and research ethics boards to aim to protect the welfare of participants, and, in some circumstances, to promote that welfare in view of any foreseeable risks associated with the research.

Confidentiality: An ethical and/or legal responsibility of individuals or organizations to safeguard information entrusted to them, from unauthorized access, use, disclosure, modification, loss or theft.

Conflict of interest: The incompatibility of two or more duties, responsibilities, or interests (personal or professional) of an individual or institution as they relate to the ethical conduct of research, such that one cannot be fulfilled without compromising another.

Consent: An indication of agreement by an individual to become a participant in a research project. The term "consent" means "free (also referred to as voluntary), informed and ongoing consent."

Continuing research ethics review (also referred to as "Continuing ethics review"): Any review of ongoing research conducted by a research ethics board (REB) occurring after the date of initial REB approval and continuing throughout the life of the project to ensure that all stages of a research project are ethically acceptable in accordance with the principles in the TCPS 2 Policy.

Core principles: The three core principles of the TCPS 2 Policy that together express the overarching value of respect for human dignity: Respect for Persons, Concern for Welfare and Justice.

Data linkage: The merging or analysis of two or more separate data sets (e.g. health information and education information about the same individuals) for research purposes.

Data safety monitoring board: A multi-disciplinary, expert advisory group established by a research sponsor, that is responsible for safeguarding the interests of research participants by reviewing emerging data, assessing the safety and efficacy of clinical trial procedures, and monitoring the overall conduct of a trial.

Debriefing: The full disclosure of the research purpose and other pertinent information to participants who have been involved in research employing partial disclosure or deception. Debriefing is typically done after research participation has ended, but may be done at any time during the study.

Delegated review: The term refers to the level of REB review assigned to minimal risk research projects. Delegated reviewers are selected from among the REB membership, with the exception of the ethics review of student course-based research, which can be reviewed by delegates from the student's department, faculty, or an equivalent level.

De-identification: means to remove from the records any information that identifies the individual or for which it is reasonably foreseeable in the circumstances that it could be utilized, either alone or with other information, to identify the individual.

Delegated Review: under a delegated review procedure, the review may be performed by the Research Ethics Board (REB) Chair and/or one or two experienced reviewers from among the REB membership. Delegated review procedures may be used for certain kinds of research involving minimal risk and for minor changes in approved research (see SOP # XXX: Delegated Review).

Emergent design: A research method in which data collection and analyses can evolve over the course of a research project in response to what is learned in earlier parts of the study.

Fetal tissue: Membranes, placenta, umbilical cord, amniotic fluid, and other tissue that contains genetic information about the fetus.

Fetus: A human organism during the period of its development beginning on the 57th day following fertilization or creation, excluding any time during which its development has been suspended, and ending at birth.

Full board review: The level of REB review assigned to above minimal risk research projects. Review is conducted by the full membership of the research ethics board and is the default requirement for the ethics review of research involving humans.

Embryo: A human organism during the first 56 days of its development following fertilization or creation, excluding any time during which its development has been suspended. It also includes any cell derived from such an organism that is used for the purpose of creating a human being.

External Safety Report: a report of a serious unexpected adverse drug reaction that occurs at any other centre involved in a multi-centre study using the same investigational agent.

Ex-Officio members: membership on the REB by virtue of a particular office or position held. The Manager and coordinator of the Research Ethics Office are ex-officio members.

GCP: Good Clinical Practice

Harm: Anything that has a negative effect on participants' welfare, broadly construed. The nature of the harm may be social, behavioural, psychological, physical or economic.

Human biological materials: Tissues, organs, blood, plasma, skin, serum, DNA, RNA, proteins, cells, hair, nail clippings, urine, saliva, and other body fluids. The term also includes materials related to human reproduction, including embryos, fetuses, fetal tissues and human reproductive materials.

- Identified human biological materials - The materials are labelled with a direct identifier (e.g. name, personal health number). Materials and any associated information are directly traceable back to a specific individual.

- Coded human biological materials – Direct identifiers are removed from the materials and replaced with a code. Depending on access to the code, it may be possible to re-identify specific individuals (e.g. a principal investigator retains a key that links the coded material with a specific individual if re-linkage is necessary).

- Anonymized human biological materials – The materials are irrevocably stripped of direct identifiers, a code is not kept to allow future re-linkage, and risk of re-identification of individuals from remaining indirect identifiers is low or very low.

- Anonymous human biological materials – The materials never had identifiers attached to them and risk of identification of individuals is low or very low.

Human genetic research: The study of genetic factors responsible for human traits and the interaction of those factors with each other, and with the environment.

ICH: GCP: International Conference on Harmonization: Good Clinical Practice Guidelines

Identifiable information: means information that identifies an individual or for which it is reasonably foreseeable in the circumstances that it could be utilized, either alone or with other information, to identify an individual. TCPS 2: Chapter 5 offers the following guidance for
assessing information which may be identifying:

- Directly identifying information – the information identifies a specific individual through direct identifiers (e.g., name, social insurance number, personal health number etc.).
- Indirectly identifying information – the information can reasonably be expected to identify an individual through a combination of indirect identifiers (e.g., date of birth, place of residence or unique personal

characteristic).

- Coded information – direct identifiers are removed from the information and replaced with a code. Depending on access to the code, it may be possible to re- identify specific participants (e.g., the principal investigator retains a list that links the participants' code names with their actual name so data can be re-linked if necessary).
- Anonymized information – the information is irrevocably stripped of direct identifiers, a code is not kept to allow future re-linkage, and risk of re- identification of individuals from remaining indirect identifiers is low or very low.
- Anonymous information – the information never had identifiers associated with it (e.g., anonymous surveys) and risk of identification of individuals is low or very low.

Incentive: Anything offered to research participants, monetary or otherwise, to encourage participation in research.

Incidental findings: Unanticipated discoveries made in the course of research that are outside the scope of the research.

Intermediary: An individual with the necessary language skills to ensure effective communication between the research team and participants should any language barriers exist.

Institutional conflicts of interest: An incompatibility between two or more substantial institutional obligations that cannot be adequately fulfilled without compromising one or another of the obligations.

Institutional Official: Senior official who signs an institution's human subjects assurance or contract agreement, making a commitment on behalf of the institution to comply with TCPS 2, PHIPA (2004) or 45 CFR Part 46 and the US Code of Federal Regulations covering protection of human subjects.

Justice: A core principle of TCPS 2 Policy that refers to the obligation to treat people fairly and equitably. Fairness entails treating all people with equal respect and concern. Equity requires distributing the benefits and burdens of research participation in such a way that no segment of the population is unduly burdened by the harms of research or denied the benefits of the knowledge generated from it.

Key File: a document that links the unique study identifier with the identifying information of the research participant.

Legally Acceptable Representative: an individual or judical or other body authorized under applicable law to consent, on behalf of a prospective participant, to the participant's participation in a research study.

Manager: refers to the Manager, Research Ethics Office who oversees the operations of the Research Ethics Office.

Medical device trials: Clinical trials that test the safety and/or efficacy of one or more devices/ instruments used in the prevention, diagnosis, mitigation, or treatment of a disease or abnormal physical condition or the restoration, correction or modification of body function or structure.

Memorandum of Understanding (MOU): The agreement between the Agencies and institutions eligible to receive and manage research funding from the Agencies. A commitment to adhere to the TCPS is a part bf the MOU.

Minimal risk research: Research in which the probability and magnitude of possible harms implied by participation in the research is no greater than those encountered by participants in the aspects of their everyday life that relate to the research.

Minor amendment/change: any change that would not materially affect an assessment of the risks and benefits of the study or does not substantially change the specific aims or design of the study.

Multi-centre study: means that the research is expected to be conducted at more than one centre.

Observational research: The study of behaviours in a natural environment in which people involved in their normal activities are observed whether with or without their knowledge. This term does not include observational methods used in epidemiological research.

Ongoing research: Research that has received REB approval and has not yet been completed.

Participant: An individual whose data, or responses to interventions, stimuli, or questions by a researcher are relevant to answering a research question; also referred to as "human participant," and in other policies/guidance as "subject" or "research subject."

Participatory research: Research that includes the active involvement of those who are the subject of the research. Participatory research is usually action-oriented, where those involved in the research process collaborate to define the research project, collect and analyze the data, produce a final product and act on the results.

Personal health information (PHI):
means identifying information about an individual in either an oral or in a recorded form, if the information

- relates to the individual's physical or mental health, including family health history
- relates to the provision of health care, including the identification of persons providing care
- is a plan of service for an individual requiring long-term care
- relates to payment or eligibility for health care
- relates to the donation of body parts or bodily substances or is derived from the testing, or examination of such parts or substances
- is the individual's Provincial health number
- Identifies an individual's substitute decision-maker.
- Any other information about an individual that is included in a record containing personal health information is also included in this definition.
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This definition does not include information about an individual if the information could not reasonably be used to identify the individual.

Placebo: is an inactive substance or intervention that resembles the comparable active substance or intervention.

Placebo-controlled trials: A clinical trial in which the safety or efficacy of one or more interventions are compared with a placebo control group.

Policy: a written statement that provides direction for decision-making, prescribes limits, identifies responsibility and accountability, and is secondary to existing legislation and bylaws. Policy statements describe what the Research Ethics Board (REB) is committed to and will typically contain words such as "must" or "will".

Principal Investigator (PI): the individual who is responsible for the overall study at the institution. The PI may be either a local Principal Investigator responsible for a single site study, or the lead investigator within

the institution for a multi-site study. An external PI leading a multi- site study must appoint a local PI as a co-investigator

Privacy: in the context of personal information, privacy is about having the ability to control or influence the way in which information about a person is collected, used and disclosed.

Privacy risks: The potential harms that participants, or the groups to which they belong, may experience from the collection, use, and disclosure of personal information for research purposes.

Procedure: written statements that typically describe a series of specific steps (action verbs) required to complete various tasks.

Proportionate review: based on the general principle that the more invasive or harmful the proposed and ongoing research, the greater the scrutiny in assessing the research. Proportionate review reserves the most intensive scrutiny, and correspondingly more protection, for the most ethically challenging research.

Psychotherapy trials: A clinical trial testing the safety and/or efficacy of one or more psychotherapeutic approaches to behavioural disorders or other mental illness.

Publicly available information: Any existing stored documentary material, records or publications, which may or may not include identifiable information, and that has no restrictions on its use or distribution, or that may be released under certain legal conditions.

Publicly declared emergency: An emergency situation which, due to the extraordinary risks it presents, has been proclaimed as such by an authorized public office (in accordance with legislation and/or public policy). Publicly declared emergencies are extraordinary events that arise suddenly or unexpectedly, and require urgent or quick responses to minimize devastation. Examples include hurricanes and other natural disasters, large communicable disease outbreaks, catastrophic civil disorders, bio-hazardous releases, environmental disasters, and humanitarian emergencies.

Qualified Investigator (QI): Medical research involving human subjects that evaluates the effects of one or more health-related interventions on health outcomes must be lead only by individuals with the appropriate ethics and scientific education, training and qualifications. Research on patients or healthy volunteers requires the supervision of a competent and appropriately qualified physician, dentist or other health care professional. For Health Canada clinical trials, QI is the person responsible to the sponsor for the conduct of the clinical trial at a clinical trial site and who is entitled to provide health care under the laws of the province, where that clinical trial site is located.

Qualitative research: An approach that aims to understand how people think about the world and how they act and behave in it. This approach requires researchers to understand phenomena based on discourse, actions, and documents, and how and why individuals interpret and ascribe meaning to what they say and do, and to other aspects of the world (including other people) they encounter.

Quorum: is defined as fifty percent (50%) plus one of voting REB members to be present. However, where there is less than full attendance, decisions will be adopted only if the members attending the meeting possess the appropriate background and expertise in the area of research being considered. In exceptional circumstances, a member may submit their written review in advance to the REB Chair, and the Chair will document their proxy vote.

Reciprocal research ethics board (REB) review: An official agreement between two or more institutions, in which they accept, with an agreed level of oversight, the research ethics reviews of each other's REBs.

Reimbursement: Payment to participants to ensure that they are not put at a direct, or indirect, financial disadvantage for the time and inconvenience of participation in research. Direct expenses refer to the costs incurred, and indirect expenses refer to losses that arise, because of research participation.

Research: An undertaking intended to extend knowledge through a disciplined inquiry or systematic investigation.

Research agreement: A document that serves as a primary means of clarifying and confirming mutual expectations and, where appropriate, commitments between researchers and communities.

Research directive: Written instructions used to express an individual's preferences for participation in future research, in the event that the individual loses capacity. It is intended to guide the individual's authorized third party in deciding whether or not to give substitute consent for the individual to participate in research.

Research ethics board (REB): A body of researchers, community members, and others with specific expertise (e.g. in ethics, in relevant research disciplines) established by an institution to review the ethical acceptability of all research involving humans conducted within the institution's jurisdiction or under its auspices.

REB Membership: the composition of the REB is outlined in the Terms of Reference following the guidance of TCPS 2: Chapter 6. It will consist of a minimum of five voting members, both men and women, including representation from each category listed below:

- two members with broad expertise in relevant research disciplines, fields and methodology
- a member knowledgeable in ethics
- a member knowledgeable in the relevant law
- a member from the community having no affiliation with the Corporation, and
- a member from the Research Ethics Office (non-voting member)

REB of Record: the Research Ethics Board that has been granted the authority for the ethics review and oversight of a research study.

REB Policy & Procedure Committee: is comprised of REO staff, and the REB Chair/members.

Research ethics education and training: The provision of materials and corresponding instruction by an institution to research ethics board (REB) members or researchers with regard to the core principles and understanding of this Policy, basic ethics standards, applicable institutional policies, and legal or regulatory requirements. This term also includes an understanding of the role and mandate of REBs and responsibilities of REB members.

Re-approval Application: written summaries of the study/research status which may include: a recruitment summary, a summary of local serious adverse events, a notification of protocol deviations requiring reporting, updated conflict of interest information, relevant ethical and scientific information outside of an amendment, attachment of the current approved informed consent form, and Data Safety Monitoring Board reports.

Research Ethics Office: an administrative service that supports the duties of the Research Ethics Board of each organization.

Research involving partial disclosure or deception: A type of research, in which the participant may not know that they are part of a project until it is over or is not informed of the true purpose of the research in advance. See "Debriefing."

Respect for Persons: A core principle of TCPS 2 Policy that recognizes the intrinsic value of human beings and the respect and consideration that they are due. It incorporates the dual moral obligations to respect autonomy and to protect those with developing, impaired, or diminished autonomy.

Risk: The possibility of the occurrence of harm. The level of foreseeable risk posed to participants by their involvement in research is assessed by considering the magnitude or seriousness of the harm and the probability that it will occur, whether to participants or to third parties.

Secondary use: The use in research of information or human biological materials originally collected for a purpose other than the current research purpose.

Security: Measures taken to protect information. It includes physical, administrative, and technical safe-guards.

Signing Authority: individual(s) authorized to sign documents on behalf of the REB. Also referred to as "Authorized signatory".

SOP: standard operating procedure. For the purpose of this document, SOP will include both policies and procedures unless otherwise specified.

SOP Template: document used to standardize the format of all standard operating policies and procedures.

SOP Index: list of the current, finalized standard operating policies and procedures for REB, members and Research Ethics Office (REO) staff.

Sponsor-Investigator: an individual who both initiates and conducts a clinical trial, and under whose immediate direction the investigational product is administered to, dispensed to, or used by a research participant. The obligations of a sponsor-investigator include both those of a sponsor and those of an investigator.

Standard REB Review Package:
includes the meeting agenda, minutes from the previous meeting, documents related to 'business arising' (e.g., PI responses for revisions/clarifications and resulting actions), REB applications and continuing ethics review (e.g., new projects, amendments, re-approvals), reports (e.g., investigator brochures, safety reports) and administrative items (e.g., REB member recruitment, update on Standard Operating Policies and Procedures).

Stopping rules: Statistically significant end points and safety considerations for a clinical trial that are determined in advance, and, once reached, dictate that the trial must be terminated.

Suspension: a temporary or permanent halt to all or part of research activities pending future action by the REB or by the investigator of his/her study personnel.

Task Delegation Log: a document that lists the delegation of trial specific duties by the Principal Investigator to other research personnel in the team.

TCPS 2: Canadian Institutes of Health Research, Natural Sciences and Engineering Research Council of Canada, and Social Sciences and Humanities Research Council of Canada, Tri-Council Policy Statement: Ethical conduct for Research Involving Humans,[December, 2010].

Termination: a permanent halt by the REB to all or some research activities.

Therapeutic misconception: A misunderstanding, on the part of participants, of the purpose, benefits, and/or risks of clinical trials. Often participants do not understand that research is aimed primarily at producing knowledge and may not provide any therapeutic benefit to them.

Traditional knowledge: The knowledge held by First Nations, Inuit and Métis peoples, the Aboriginal peoples of Canada. Traditional knowledge is specific to place, usually transmitted orally, and rooted in the experience of multiple generations. It is determined by an Aboriginal community's land, environment, region, culture, and language. It may also include new knowledge transmitted to subsequent generations.

Training Record: document used to document the training for REB members and REO staff.

Unanticipated issues: Issues that occur during the conduct of research; may increase the level of risk to participants or have other ethical implications that may affect participants' welfare; and were not anticipated by the researcher in the research proposal submitted for research ethics review.

Undue influence: The impact of an unequal power relationship on the voluntariness of consent. This may occur when prospective participants are recruited by individuals in a position of authority over them (e.g. doctor/patient, teacher/student, and employer/employee). See "Coercion."

Unique Study Identifier: a unique number or unique combination of letter, numbers and/or symbols used to identify a research participant. Also known as a "unique study code".

Vulnerable Population: Vulnerability is often caused by limited capacity (temporary or permanent), or limited access to social goods, such as rights, opportunities and power. Individuals or groups in vulnerable circumstances have historically included children, the elderly, women, prisoners, those with mental health issues and those with diminished capacity for self-determination. Ethno-cultural minorities and those who are Institutionalized are other examples of groups who have at times been treated unfairly and inequitably in research. (TCPS 2, page 10). Vulnerability needs to be assessed within the context of the proposed research.

Welfare: The quality of a person's experience of life in all its aspects. Welfare consists of the impact on individuals and/or groups of factors such as their physical, mental and spiritual health, as well as their physical, economic and social circumstances.

Responsibility:
REB Chair, REB members
REB office
Senior Management
Board of Directors

References:

1) Research Ethics Board Standard Operating Procedures, St Joseph's Care Group May 2012

2) Canadian Institutes of Health Research, Natural Sciences and Engineering Research Council of Canada, and Social Sciences and Humanities Research Council of Canada, Tri-Council Policy Statement: Ethical conduct for Research Involving Humans, December 2010: (short name: TCPS 2) http://www.pre.ethics.gc.ca/eng/policy-politique/initiatives/tcps2-eptc2/Default/

3) ICH: E6 - Guidance for industry: Good Clinical Practices (GCP): (April 1996) http://www.fda.gov/downloads/Drugs/Guidances/ucm073122.pdf

4) Health Canada: Therapeutic Products Directorate Food and Drug Regulations for Clinical Trials: Part

C: DRUGS (Division 5)
http://www.hc-sc.gc.ca/dhp-mps/prodpharma/applic-demande/guide-ld/clini/ctdcta_ctddec-eng.php

5) Personal Health Information Protection Act, 2004:
http://www.e-laws.gov.on.ca/html/statutes/english/elaws_statutes_04p03_e.htm

6) US http://www.e-laws.gov.on.ca/html/statutes/english/elaws_statutes_04q03_e.htm Food and Drug Administration (FDA) Code of Federal Regulations (CFR), Title 21, Parts 56.108, 56.115
http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfcfr/CFRSearch.cfm?CFRPart=56

7) U.S. Department of Health and Human Services (HHS): Code of Federal Regulations (CFR), Title 45 Part 46.103, Part 46.108
http://www.hhs.gov/ohrp/humansubjects/guidance/45cfr46.html

8) U.S. Department of Health and Human Services (HHS): Office for Human Research Protections (OHRP) Policy & Guidance Library
http://www.hhs.gov/ohrp/policy/index.html

9) Ontario Shores Research Ethics Board Terms of Reference, Functions and Responsibilities (2009)

10) All applicable policies and procedures, protocols and guidelines